



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900- AQ46

Veterans Community Care Program - Organ and bone marrow transplant care.

AGENCY: Department of Veterans Affairs.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: On February 22, 2019, the Department of Veterans Affairs (VA) published a proposed rulemaking to amend its regulations on the provision of necessary hospital care, medical services, and extended care services from non-VA entities or providers in the community. This supplemental notice of proposed rulemaking (SNPRM) provides clarification about the process to be used to make decisions regarding organ and bone marrow transplant care.

DATES: Comments must be received by VA on or before [INSERT DATE 15 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted by through <http://www.Regulations.gov>; by mail or hand-delivery to Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, N.W., Room 1063B, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AQ46, Veterans Community Care Program; Supplemental notice of proposed rulemaking”. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This

is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Office of Community Care (10D), Veterans Health Administration, Department of Veterans Affairs, Ptarmigan at Cherry Creek, Denver, CO, 80209; Joseph.Duran2@va.gov, (303) 370-1637. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On February 22, 2019, VA published a proposed rulemaking to amend its regulations on the provision of necessary hospital care, medical services, and extended care services from non-VA entities or providers in the community. Federal Register (84 FR 5629). That rulemaking proposed to define and implement the new Veterans Community Care Program authorized by section 1703 of title 38, United States Code (U.S.C.), as that statute will be amended by section 101 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, effective upon VA's issuance of implementing regulations. For the sake of convenience and understanding, we will refer to provisions of section 1703, as section 101 of the MISSION Act will amend it, although we recognize that section 1703 as so amended is not legally effective until VA has published a final rule implementing the Veterans Community Care Program. The Veterans Community Care Program will permit eligible veterans to elect to receive hospital care, medical services, and extended care services from eligible entities and providers. VA asked for comments on the proposed rule on or before March 25, 2019. In that proposed rule, we noted that we did

not include language to address the provisions in section 1703(l) regarding organ and bone marrow transplants. We advised that we would address this through a subsequent rulemaking. This rulemaking proposes to implement section 1703(l). We propose to modify § 17.4020, as proposed in VA's earlier proposed rulemaking, by amending paragraph (a) and adding a paragraph (d) to that section to govern decisions regarding organ and bone marrow transplant care..

Background on VA Transplant Program

To help the public better understand the effect of this supplemental notice of proposed rulemaking and this provision of law, we offer some additional background on both VA's transplant program and transplants in general. We believe this information would be helpful to the public by providing context for how transplant care is furnished by VA today and how the Organ and Procurement Transplantation Network operates. Some of the following discussion is excerpted and edited from an article by Dr. William Gunnar, "The VA Transplant Program: A Rebuttal to Criticism and a Look to the Future", published online by the American Journal of Transplantation on February 12, 2019, cited as doi: 10.1111/ajt.15295.

The VA Transplant Program (VATP) was established decades ago during initial development of solid organ transplantation in the United States. It is well resourced, provides timely and high quality solid organ transplant care and services to the nation's veterans, and supports research and education missions of VA and affiliated academic medical centers. Access and outcomes data for fiscal years (FY) 2014-2018 show that the VATP received 12,801 solid organ and bone marrow transplant referrals (10,494

solid organ and 2,307 bone marrow), added 3,972 veterans to the Organ Procurement and Transplantation Network (OPTN) waitlist, and performed 1,699 solid organ transplants (180 heart, 748 kidney, 694 liver, and 77 lung). Timeliness to transplant evaluation within 30 days from referral was over 98 percent in FY 2018. Thirty-day and one-year survival rates for veterans receiving a transplant during the 10-year period from October 1, 2008, to September 30, 2018, were 98.0 percent and 93.5 percent respectively for heart, 99.9 percent and 97.5 percent respectively for kidney; 97.7 percent and 90.5 percent respectively for liver; and 98.8 percent and 88.4 percent respectively for lung. Outcomes were on par or better than national data made publicly available by the Scientific Registry of Transplant Recipients. VATCs have leveraged VA specialty programs for veteran-prevalent diseases, such as posttraumatic stress disorder, to better ensure transplant candidacy for high-risk patients and to provide support to optimize post-transplantation outcomes.

The VATP is comprised of the following VA Transplant Centers (VATC): five heart (Madison, Wisconsin; Nashville, Tennessee; Palo Alto, California; Richmond, Virginia; and Salt Lake City, Utah); seven kidney (Birmingham, Alabama; Bronx, New York; Houston, Texas; Iowa City, Iowa; Nashville, Tennessee; Pittsburgh, Pennsylvania; and Portland, Oregon); six liver (Houston, Texas; Madison, Wisconsin; Nashville, Tennessee; Pittsburgh, Pennsylvania; Portland, Oregon; and Richmond, Virginia); and two lung (Madison, Wisconsin; and Seattle, Washington). Three additional VATCs are planned for activation in FY 2019: one kidney transplantation program; one heart transplantation program; and one program for heart and lung transplants.

All VATCs are members of the OPTN and abide by OPTN policy. Some VATCs perform all transplantation care within VA as “in-house” programs and are independent OPTN members. Others are integrated with an academic medical center which is an OPTN member. These integrated VATCs have established infrastructure to provide pre- and post-transplant care at the VA medical facility, but transplant procedures are performed at the affiliate. Each VATC also supports veterans who transition transplantation care to VA after having received transplant procedures in the community.

VA policy establishes a standardized process for veteran referral to the VATP in order to facilitate timely and high-quality care. The referring VA medical facility submits veteran health information into a secure intranet-based application called Transplant Referral and Cost Evaluation/Reimbursement (TRACER, developed and implemented in 2013), the referring medical facility selects a VATC with patient concurrence, and TRACER then notifies the VATC. The VATC reviews the information and submits an initial review decision as to whether the clinical information supports further evaluation. Emergency referrals are decided within 48 hours and stable referrals within 5 business days. When referrals are accepted, the VATC completes an evaluation within 30 calendar days of the referral submission date for stable patients; emergency referrals may require transfer to the VATC for inpatient management and listing. Following evaluation and determination that the veteran is a transplant candidate, the VATC directs transplant-related care, orders additional testing as needed, and waitlists the veteran with OPTN when the candidate’s clinical status is deemed appropriate. Each VATC is responsible for veteran transplant care and compliance with OPTN policy

including maintenance of program-specific eligibility criteria. VA program offices do not dictate VATC clinical decisions. TRACER facilitates the referral process and tracks dates for VATC initial review decision, evaluation, OPTN waitlisting, and transplantation. Referring medical facilities may request a second opinion in TRACER if the primary VATC deems the veteran not-eligible for transplantation at its program. The referring medical facility may also submit an appeal to VA in TRACER if both primary and second VATC determinations are that the patient is not-eligible for transplantation. Appeals are reviewed by a national Transplant Surgical Advisory Board, and veterans deemed not eligible through the appeal process may be resubmitted to TRACER when clinical conditions change. TRACER also supports dual-OPTN listing at two transplant centers in response to requests by patients via referring facilities or VATCs.

Each veteran and her or his caregiver, as well as a living donor and living donor caregiver, if applicable, are supported with travel and lodging to and from home and the VATC for pre-operative evaluation, pre-operative testing or in-hospital care, the transplant procedure, the immediate post-transplant recovery, and necessary post-operative care and treatment. Evaluations for candidacy, wait-list management, and post-transplantation care may be completed using telehealth, thereby keeping the veteran close to home (or providing certain care in home). In fiscal year 2018, 12.7 percent of cardiac evaluations, 22.1 percent of kidney evaluations, 25.8 percent of liver evaluations, and 78.7 percent of lung evaluations were completed through telehealth. Veteran candidates can communicate with the VATC team through video connected care and secure messaging. Additional information regarding the VATP referral

process can be found on the following website:

<https://www.va.gov/health/services/transplant/>.

VATCs typically require veterans to travel for transplant procedures or for care when telehealth is not appropriate or desired by the veteran. Inequalities in geographic access to solid organ transplantation exist in the United States, are not limited to veterans enrolled in VA, and require many non-veterans to travel. Transplant care is complicated, and every transplant center requires significant resources that are simply unavailable in certain parts of the country. Four States are without an established transplant center (VA or non-VA); 14 States do not have a liver transplant center; 15 States do not have a cardiac transplant center; and 22 States do not have a lung transplant center. Prior studies suggest that distance to a transplant center may adversely impact access to transplant service, mortality on the OPTN waitlist, and transplant outcomes. Non-veteran patients living in small towns and isolated rural regions are 8-15 percent less likely to be placed on a waitlist and 10-20 percent less likely to undergo heart, kidney, and liver transplantation than patients in urban environments. For perspective, approximately 2.8 million VA enrolled veterans (approximately 31 percent) reside in a rural or highly rural location.

TRACER data identifies that referrals from VA medical facilities located less than 100 miles from the selected VATC experienced shorter average times for initial decision review, evaluation, and placement on the OPTN waitlist. A majority of these patients receive other care at the VATC and are “self-referred” by the facility through TRACER to the VATC. No statistically significant differences were identified in heart, kidney, liver, or lung referral timeliness to initial decision review, evaluation, or placement on the

OPTN waitlist for distances of 100-300 miles, 301-500 miles, and greater than 500 miles. Distance between the referring VA medical facility and the VATC, including distances less than 100 miles and greater than 500 miles, was not found to impact the rate of mortality on the OPTN waitlist, time to transplantation, or post-transplant survival. While travel distance may impact veteran or caregiver satisfaction, there is no demonstrated impact on key clinical outcomes.

In addition to the clinical transplantation care provided to veterans, VATCs have significant impacts on the academic missions of VA and affiliated medical centers. Nearly all VATC physicians hold faculty appointments at affiliated academic centers; most are involved in graduate medical education; and several participate in basic science or clinical research related to transplantation. Trainees at VATCs, both students and residents, benefit from participation in transplantation care of veterans and include surgery, general medicine, medical subspecialties, behavioral health, nursing, and pharmacy. Numerous research studies and publications from VATCs have addressed transplantation-related care, disease mechanisms, and clinical outcomes for veterans.

Proposed Changes to § 17.4020 for Organ and Bone Marrow Transplants

First, we would amend §17.4020(a), as proposed in VA's earlier proposed rulemaking. As initially proposed § 17.4020(a) would incorporate a provision from the Veterans Choice Program at § 17.1515(a) related to a covered veteran's election to receive care in the community. This provision would be carried over to the Veterans Community Care Program to confirm a veteran's ability to elect to receive community

care under appropriate circumstances, consistent with section 1703(d)(3). The change proposed in this supplemental notice of proposed rulemaking (SNPRM) would amend § 17.4020(a), as it was proposed in VA's earlier proposed rulemaking, to create an exception to the ability to elect to receive non-VA care for organ and bone marrow transplants in paragraph (d), as further described below.

Proposed § 17.4020(d) would implement section 1703(l), related to organ and bone marrow transplants. Section 1703(l) states that VA must determine whether to authorize an organ or bone marrow transplant for a covered veteran at a non-VA facility in the case of a covered veteran in need of an organ or bone marrow transplant who has, in the opinion of the primary care provider of the veteran, a medically compelling reason to travel outside of the region of the Organ Procurement and Transplantation Network (OPTN) in which the veteran resides. (OPTN matches organs with transplant candidates on waiting lists in need of transplantation, but does not regulate bone marrow transplantation. Regions have been used to facilitate transplantation and communication among OPTN member organizations.) While section 1703(d)(3) generally provides that a covered veteran who is determined by VA to meet eligibility criteria in 1703(d)(1) has the ability to decide whether to receive care in the community, section 1703(l) expressly provides to the Secretary the authority to decide whether to authorize organ or bone marrow transplant care in the community for certain veterans, specifically those who require an organ or bone marrow transplant and who have, in the opinion of the primary care provider of the veteran, a medically compelling reason to travel outside of the OPTN region in which the veteran resides.

Section 1703(l) qualifies determinations under section 1703(d) and (e) for these veterans. It is a well-accepted principle of statutory construction that a more specific provision is read to qualify a more general provision in a law. Congress often states general principles that are further qualified or revised in other provisions of law. Sections 1703(d) and 1703(l) fit this model. Section 1703(d) establishes a general rule that covered veterans who satisfy one of the conditions for eligibility are able to elect to have VA authorize their care in the community or to schedule an appointment with a VA provider. Section 1703(l) inverts this decision making and states unequivocally that the Secretary makes the determination of whether to authorize community care for covered veterans requiring an organ or bone marrow transplant and who have a medically compelling reason to travel outside of the OPTN region in which they reside to receive the transplant. For any other type of health care, section 1703(d) controls, and the covered veteran's election is binding on VA. For those veterans described in section 1703(l), however, this provision of law controls. If section 1703(d) applied to covered veterans described in section 1703(l), then section 1703(l) would have no meaning or effect. There is a strong presumption against reading a provision of law that would render other provisions of the statute superfluous or unnecessary. Reading section 1703(d) to authorize covered veterans described in section 1703(l)(2) to determine where to receive their care would render section 1703(l)(1) meaningless, and therefore such a reading should be rejected.

We wish to be clear on the effect of section 1703(l). The Secretary's discretion is limited to covered veterans who: (1) meet one or more of the eligibility criteria under proposed § 17.4010; (2) require an organ or bone marrow transplant; and (3) have a

medically compelling reason to travel outside the OPTN region in which the veteran resides to receive such a transplant. The first condition has already been described in VA's earlier proposed rule. The second condition, requiring an organ or bone marrow transplant (as required by section 1703(l)(2)(A)), would be satisfied when VA has determined that a transplant is clinically necessary and appropriate. For the third condition, we propose to regulate the factors that would be considered when a medically compelling reason to travel outside the OPTN region in which the veteran resides exists. However, before describing these factors, we wish to provide some examples to illustrate the scope of this authority.

We note initially that this section only applies for a covered veteran (as defined in § 17.4005) who meets one or more of the eligibility criteria under §17.4010. If, for example, a covered veteran resided near a VATC that could furnish the care within the designated access standards proposed under §17.4040 and no other eligibility criterion applied, the veteran would not be eligible to elect to have VA authorize their care in the community. If the veteran was eligible for care in the community under one or more of the eligibility criteria, and if the veteran did not have a medically compelling reason to travel outside the OPTN region in which the veteran resided, the veteran's election would control because the Secretary would not have the discretion conferred by section 1703(l). Take, as an example, a veteran who lived more than a 60 minute average driving time from a VATC within the OPTN region in which the veteran resides. If a VATC were within the veteran's OPTN region, and assuming this was a typical case, it is very likely that the VATC could furnish the transplant care safely, timely, and effectively, with relatively little travel burden. Given these facts, there would likely be no

medically compelling reason to travel outside the OPTN region for the transplant care due to the availability of the VATC. Therefore, it would be up the veteran to decide whether to receive care from a community transplant center or through a VATC.

Proposed section 17.4020(d)(1) would state that, in the case of a covered veteran described in paragraph (d)(3), VA would determine whether to authorize an organ or bone marrow transplant for the covered veteran through an eligible entity or provider. This language is entirely consistent with section 1703(l)(1). Proposed section 17.4020(d)(3) would restate the language in 1703(l)(2) to provide that this paragraph would only apply to a covered veteran who met one or more conditions of eligibility under section 17.4010(a) and (1) required an organ or bone marrow transplant, and (2) has, in the opinion of the primary care provider of the veteran, a medically compelling reason to travel outside the region of the Organ Procurement and Transplantation Network in which the veteran resides, to receive such transplant.

VA would, in section 17.4020(d)(3)(i), clarify that VA would determine, based upon generally-accepted medical criteria, whether an organ or bone marrow transplant is likely to be indicated. These generally-accepted medical criteria include the exercise of some clinical discretion, which we do not purport or intend to regulate, but which are generally known by recognized medical experts and accredited transplant centers. Such criteria are those commonly accepted across the country as related to general suitability and qualification for a transplant from any provider. These criteria would support decision making for comprehensive transplantation evaluation. VA understands that each OPTN member organ transplant center and each bone marrow transplant center determines transplant suitability of each patient for its program in consideration of

patient and program factors. Each transplant center must define and apply its own eligibility criteria in consideration of individual patients. Current VA process supports veterans having a formal evaluation by at least two transplant centers, and published policy also defines an appeal process with review by a multidisciplinary Transplantation Surgery Advisory Board to ensure that patients receive due consideration for transplantation.

Proposed section 17.4020(d)(2) would provide a non-exhaustive list of factors for consideration in making determinations as to whether: (1) there is a medically compelling reason to travel outside the OPTN region, and (2) organ or bone marrow transplant care would be provided in the community. We emphasize that decisions should be personalized in consideration of the veteran's preference and health care needs but balanced with efforts to ensure high-quality care. There would be four factors to consider in both determinations. First, specific patient factors would be considered. We would not expressly describe specific factors in the interest of avoiding the regulation of medical practice, but we offer a few examples here for understanding and reference. For example, it may be relevant to consider the characteristics of disease processes which might warrant care in specific transplantation programs. Certain disease indications for transplant warrant referral to sub-specialty centers with particular expertise for that disease process. Another factor could be patient preferences regarding waitlist time and organ availability. Characteristics of waitlists including mortality rate and time to transplant will be considered for shared decision making with veterans. Yet another factor may be access to specialty support programs for the unique needs of the individual veteran; and comprehensive care coordination. Many

veterans requiring transplants also face other health issues, including substance use disorder, posttraumatic stress disorder, and other mental health disorders. The ability to address the totality of these conditions in an integrated, supportive, and patient-centered manner is often critical for the patient's health, candidacy for transplantation, and successful post-transplantation outcomes.

Second, VA and the primary care provider would consider which facilities meet VA's standards for quality, including quality metrics and outcomes, for the required transplant. This reflects VA's responsibility to ensure veterans receive high quality care. We note that VA is required by section 1703C to establish standards for quality, and these standards and their respective quality metrics (which are consistent with industry standard metrics) would be used to help inform VA's determination. Additionally, VA would assess the effectiveness of transplantation care using publicly-reported risk-adjusted outcomes of patient and graft survival, such as Scientific Registry of Transplantation Recipients data for solid organ transplantation programs.

Third, VA and the primary care provider would consider the travel burden on covered veterans based upon their medical conditions and the geographical location of eligible transplant centers. This would allow consideration of the realities of long travel distances for veterans who have advanced disease processes, who reside in locations without any qualified transplant centers, or whose caregivers are unduly burdened by travel. As noted in the section of this SNPRM providing background information on the VATP, many Americans face considerable travel distances or driving times when seeking transplant care.

Finally, VA and the primary care provider would consider the timeliness of transplant center evaluations and management. In some transplant cases, time for evaluation and waitlisting is a critical factor affecting patient outcomes and health and well-being.

Cumulatively, these factors would allow VA to make determinations on whether to provide transplantation care in the community and primary care providers to determine whether there is a medically compelling reason to travel outside the OPTN region of the veteran's residence. This list of factors is not intended to be exhaustive, as each transplant case is unique and VA needs to maintain flexibility to ensure that covered veterans receive the best and most appropriate care. We note that any covered veteran who disagreed with VA's determination could appeal this determination through VA's clinical appeals process.

As a general matter, a veteran's primary care provider may not, and often will not, be the health care provider who is actively managing the patient's transplant care needs, nor will the primary care provider necessarily have an understanding of the unique needs faced by veterans requiring a transplant. While section 1703(l) establishes that the determination of a medically compelling reason to travel outside the OPTN region in which the veteran resides is made by the primary care provider, we believe in practice, this will be made in consultation with the appropriate specialists that are evaluating the covered veteran and managing the patient's transplant needs.

We note that section 153 of the MISSION Act added a new section 1788 to title 38, United States Code, specifically authorizing VA to provide for an operation on a live donor to carry out a transplant procedure for an eligible veteran, notwithstanding that

the live donor may not be eligible for VA health care. VA will issue separate regulations concerning this new authority, and the preceding discussion is not dependent upon the promulgation of such regulations. Any comments on care for living donors will be considered outside the scope of this rulemaking.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by the proposed rulemaking at 84 FR 5629 and this SNPRM, would represent the exclusive legal authority on this subject. No contrary guidance or procedures would be authorized. All VA guidance would be read to conform with the proposed rulemaking at 84 FR 5629 and this SNPRM if possible or, if not possible, such guidance would be superseded by this SNPRM and the proposed rulemaking at 84 FR 5629.

Paperwork Reduction Act

This SNPRM contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this SNPRM would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. Although some eligible entities or providers that would furnish care and services to veterans under this rule might be

considered small entities, there would be no significant adverse economic impact. To the extent there is any impact on small entities, it would be a potential increase in business due to proposed expanded eligibility for non-VA care. Therefore, pursuant to 5 U.S.C. 605(b), these amendments would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB) as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations

of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that the action would be an economically significant regulatory action under Executive Order 12866, because it will have an annual effect on the economy of \$100 million or more. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its regulatory impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for "VA Regulations Published." This SNPRM is expected to be an EO 13771 regulatory action. Details on the estimated costs of this rule can be found in the rule's regulatory impact analysis.

Executive Order 12866 also directs agencies to "in most cases . . . include a comment period of not less than 60 days." This SNPRM would address one provision for the new Veterans Community Care Program. Providing a comment period of 15 days would allow the Secretary to ensure the provisions of this SNPRM can be finalized with the regulations for the rest of the new Veterans Community Care Program at the same time. This would ensure a smooth transition from the current Veterans Choice Program that will expire on June 6, 2019, and prevent lapses in regulatory authority for VA's national community care program. Delays in implementation of the Veterans Community Care Program and provisions related to organ and bone marrow transplants arising because the regulatory standards and guidelines were not in place by June 6, 2019, would result in inconsistent decision making that could harm veterans' health

outcomes. Having clear, consistent criteria is essential to ensuring that veterans receive the right care in the right place at the right time. Moreover, we believe that VA community care is now a familiar benefit to the public and that providing 15 days would still be a sufficient period of time for the public to comment on this single aspect of the new Veterans Community Care Program. In sum, providing a 60-day public comment period would be against public interest and contrary to the health and safety of eligible veterans. For the above reasons, the Secretary issues this rule with a public comment period of 15 days.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This SNPRM would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.009, Veterans Medical Care Benefits; and 64.018, Sharing Specialized Medical Resources.

List of Subjects in 38 CFR part 17

Administrative practice and procedure, Government contracts, Health care, Health facilities, Health professions, Health records, Reporting and recordkeeping requirements, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on February 28, 2019, for publication.

Dated: April 2, 2019

Consuela Benjamin,
*Regulations Development Coordinator,
Office of Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.*

For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

PART 17 -- MEDICAL

1. The general authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

2. Add § 17.4020 to read as follows:

§ 17.4020 Authorized non-VA care.

(a) Electing non-VA care. Except as provided for in paragraph (d) of this section, a covered veteran eligible for the Veterans Community Care Program under § 17.4010 may choose to schedule an appointment with a VA health care provider, or have VA authorize the veteran to receive an episode of care for hospital care, medical services, or extended care services from an eligible entity or provider when VA determines such care or services are clinically necessary.

(b) Selecting an eligible entity or provider. A covered veteran may specify a particular eligible entity or provider. If a covered veteran does not specify a particular eligible entity or provider, VA will refer the veteran to a specific eligible entity or provider.

(c) Authorizing emergency treatment. This paragraph (c) applies only to emergency treatment furnished to a covered veteran by an eligible entity or provider when such treatment was not the subject of an election by a veteran under paragraph (a) of this section. This paragraph (c) does not affect eligibility for, or create any new

rules or conditions affecting, reimbursement for emergency treatment under section 1725 or 1728 of title 38, United States Code.

(1) Under the conditions set forth in this paragraph (c), VA may authorize emergency treatment after it has been furnished to a covered veteran. For purposes of this paragraph (c), “emergency treatment” has the meaning defined in section 1725(f)(1) of title 38, United States Code.

(2) VA may only authorize emergency treatment under this paragraph (c) if the covered veteran, someone acting on the covered veteran’s behalf, or the eligible entity or provider notifies VA within 72-hours of such care or services being furnished and VA approves the furnishing of such care or services under paragraph (c)(3) of this section.

(3) VA may approve emergency treatment of a covered veteran under this paragraph (c) only if:

(i) The veteran is receiving emergency treatment from an eligible entity or provider.

(ii) The notice to VA complies with the provisions of paragraph (c)(4) of this section and is submitted within 72 hours of the beginning of such treatment.

(iii) The emergency treatment only includes services covered by VA’s medical benefits package in §17.38 of this part.

(4) Notice to VA must:

(i) Be made to the appropriate VA official at the nearest VA facility;

(ii) Identify the covered veteran; and

(iii) Identify the eligible entity or provider.

(d) Organ and bone marrow transplant care. (1) In the case of a covered veteran described in paragraph (d)(3) of this section, the Secretary will determine whether to authorize an organ or bone marrow transplant for the covered veteran through an eligible entity or provider.

(2) The Secretary will make determinations under paragraph (d)(1) of this section, and the primary care provider of the veteran will make determinations concerning whether there is a medically compelling reason to travel outside the region of the Organ Procurement and Transplantation Network in which the veteran resides to receive a transplant, in consideration of, but not limited to, the following factors:

(i) Specific patient factors.

(ii) Which facilities meet VA's standards for quality, including quality metrics and outcomes, for the required transplant.

(iii) The travel burden on covered veterans based upon their medical conditions and the geographic location of eligible transplant centers.

(iv) The timeliness of transplant center evaluations and management.

(3) This paragraph (d) applies to covered veterans who meet one or more conditions of eligibility under § 17.4010(a) and:

(i) Require an organ or bone marrow transplant as determined by VA based upon generally-accepted medical criteria; and

(ii) Have, in the opinion of the primary care provider of the veteran, a medically compelling reason, as determined in consideration of the factors described in paragraph (d)(2) of this section, to travel outside the region of the Organ Procurement and Transplantation Network in which the veteran resides, to receive such transplant.